



PTO/SB/21 (08-03)

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/613,222
	Filing Date	July 3, 2003
	First Named Inventor	Rubinfeld
	Art Unit	1645
	Examiner Name	Unassigned
Total Number of Pages in This Submission	Attorney Docket Number	12636-330.201

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC)
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<b>SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT</b>		
Firm or Individual name	Maya Skubatch, Reg. No. 52,505 WILSON SONSINI GOODRICH & ROSATI Customer No. 021971	
Signature		
Date	12/5/03	

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PATENT

Attorney Docket No. 12636-330.201

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application	)	<u>PATENT APPLICATION</u>
	)	
Inventor(s): Rubinfeld	)	
	)	Art Unit: 1645
Application No.: 10/613,222	)	
	)	Examiner: Unassigned
Filed: July 3, 2003	)	
	)	
Title RESTORING CANCER-SUPPRESSING	)	
FUNCTIONS TO NEOPLASTIC CELLS	)	
THROUGH DNA HYPOMETHYLATION	)	
(AS AMENDED)	)	

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**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97**

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy of each listed publication and U.S. and foreign patent, except for pending U.S. applications, is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

☒ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):

- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --  
☐ (2) It is being filed within 3 months of entry of a national stage  
-- OR --  
☒ (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --  
☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

☐ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:

- ☐ a certification as specified in §1.97(e) is provided below; **or**  
☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:

- A. a certification as specified in §1.97(e) is completed below; and  
B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**  
C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☒ **Fee Authorization.** The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.12636-330.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 12/4/03

650 Page Mill Road  
Palo Alto, CA 94304-1050  
(650) 493-9300  
Customer No. 021971

By: Maya Skubatch  
Maya Skubatch  
Reg. No. 52,505



PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application No.	10/613,222
				Filing Date	July 3, 2003
				First Named Inventor	Rubinfeld
				Art Unit	1645
				Examiner Name	Unassigned
Sheet	1	Of	2	Attorney Docket No.	12636-330.201

OTHER PRIOR ART – NON PATENT RELATED DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published	T <sup>2</sup>
		Debusscher et al., Phase I-II Trial of 5-AZA-2'-Deoxycytidine in Adult Patients with Acute Leukemia, <i>Leukemia Research</i> , Vol. 5, pp. 131-142, 1981	
		Kantarjian et al, Decitabine Studies in Chronic and Acute Myelogenous Leukemia, <i>Leukemia</i> , Vol. 11, Supp. 1, pp. S35-S36, 1997.	
		Kantarjian et al., Results of Decitabine Therapy in the Accelerated and Blastic Phases of Chronic Myelogenous Leukemia, <i>Leukemia</i> , Vol. 11, Supp. 1, pp. 1617-1620, 1997.	
		Koshy et al., 2-Deoxy 5-Azacytidine and Fetal Hemoglobin Induction in Sickle Cell Anemia, <i>Blood: The Journal of The American Society of Hematology</i> , Vol. 96, No. 7, pp. 2379-2384, 2000.	
		Momparler et al, Clinical Trial on 5-AZA-2'-Deoxycytidine in Patients with Acute Leukemia, <i>Pharmac. Ther.</i> , Vol. 30, pp. 277-286, 1985.	
		Momparler et al., 5-AZA-2'-Deoxycytidine Therapy in Patients with Acute Leukemia Inhibits DNA Methylation, <i>Leukemia Research</i> , Vol. 8, No. 2, pp. 181-185, 1984.	
		Pinto et al., 5-AZA-2'-Deoxycytidine as a Differentiation Inducer in Acute Myeloid Lukaemias and Myelodysplastic Syndromes of the Elderly, <i>Bone Marrow Transplantation</i> , Vol. 4, Supp. 3, pp. 28-32, 1989.	
		Pinto et al., 5-AZA-2'-Deoxycytidine as a Differentiation Inducer in Human Hemopoietic Malignancies: Preliminary Observations on the <i>in vivo</i> Modulation of Leukemia Cell Phenotype and Correlations with Clinical Response, <i>Leukemia Research</i> , Vol. 8, pp. 143-164, 1984	
		Rivard et al., Phase I Study on 5-AZA-2'-Deoxycytidine in Children with Acute Leukemia, <i>Leukemia Research</i> , Vol. 5, No. 6, pp. 453-462, 1981.	
		Sacchi et al., Decitabine, a Hypomethylating Agent, is Active for the Treatment of Chronic Myelogenous Leukemia (CML) in Non-Lymphoid Blastic Phase (BP), <i>Blood: The Journal of The American Society of Hematology</i> , Vol. 92, No. 10, Supp. 1, pp. 252a, 1998.	
		Schwartsmann et al., (5-AZA-2'-Deoxycytidine; DAC) Plus Daunorubicin as a First Line Treatment in Patients With Acute Myeloid Leukemia: Preliminary Observations, <i>Leukemia</i> , Vol. 11, Supp. 1, pp. S28-S31, 1997.	
		Wijermans et al., Continuous Infusion of Low-Dose 5-AZA-2'-Deoxycytidine in Elderly Patients with High-Risk Myelodysplastic Syndrome, <i>Leukemia</i> , Vol. 11, Supp. 1, pp. i-5, 1997.	
EXAMINER SIGNATURE		DATE CONSIDERED	

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				Examiner Name	Unassigned
Sheet	2	Of	2	Attorney Docket No.	12636-330.201

**OTHER PRIOR ART – NON PATENT RELATED DOCUMENTS**

		Wijermans et al., DNA Demethylating Therapy in MDS: The Experience with 5-AZA-2'-Deoxycytidine (Decitabine), <i>Blood: The Journal of The American Society of Hematology</i> , Vol. 94, No. 16, Supp. 1, pp. 306a, 1999	
		Wijermans et al., Low-Dose 5-AZA-2'-Deoxycytidine, a DNA Hypomethylating Agent, for the Treatment of High-Risk Myelodysplastic Syndrome: A Multicenter Phase II Study in Elderly Patients, <i>Journal of Clinical Oncology</i> , Vol. 18, No. 5, pp. 956-962, 2000.	
		Willemze et al., A Randomized Phase II Study on the Effects of 5-AZA-2'-Deoxycytidine Combined with Either Amsacrine or Idarubicin in Patients with Relapsed Acute Leukemia: an EORTC Leukemia Cooperative Group Phase II Study (06893), <i>Leukemia</i> , Vol. 11, Supp. 1, pp. S24-S27, 1997.	
		Zagonel et al., 5-AZA-2'-Deoxycytidine (Decitabine) Induces Trilineage Response in Unfavourable Myelodysplastic Syndromes, <i>Leukemia</i> , Vol. 7, Supp. 1, pp. 30-35, 1993.	
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